

A Literature Review of Instructional Requirements when Requesting Consent to Use Aborted Fetuses in Research

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Abstract

Regulation of the use of tissue from aborted human fetuses for research is enforced by various countries and by international organizations such as the World Medical Association and the Council of Europe. Common requirements for permissible use are 1) approval by the relevant institutional ethics committee, 2) determination of donation of fetal tissue after the decision to abort, and 3) consent of the donor. Some guidelines require that the father also must consent to the fetal tissue donation, but in all cases, the woman's consent is essential.

This paper surveys instructional requirements of donation systems pertaining to the use of fetal tissue. A survey of the literature found that: 1) women who are potential donors are often not in a confidential setting where they can frankly and informally discuss donating fetal tissue with the people around them and collect ideas, 2) women want to know the intended use of the fetal tissue and the overall nature of the research, 3) although the information needed to comprehend the research is sorely lacking in the donation instructions, women may nevertheless make decisions under pressure.

On the basis of these results, potential donors understandably think they should be provided with information enabling them to make an informed decision they can live with, without reservations. For these reasons, explanations currently considered "sufficient" should be reexamined to determine whether they are truly satisfactory.

Keywords: donation of fetal tissue, decision making, consent

Introduction

The world's first study on the use of fetal tissue in research was England's Peel Report (1972).¹ Its findings in sections 7 to 17 covered fetal tissue use in the fields of virology, oncology, immunology, and congenital deformities. In Appendix 2 of the Peel Report, additional domains of research using human fetal tissue include general fetal metabolism, endocrinology, hematology, cardiology, alimentary tract, renal and urinary tract, skin, amniotic fluid physiology, placental metabolism, chromosome studies, and anatomy.

According to an in-depth summary by Hiratsuka,² since the publication of an article in 1987³ reporting that the transplantation of fetal cells into patients with Parkinson's disease was effective for nerve regeneration, global interest in the use of fetal cells increased. For instance, today, fetal cartilage is transplanted into articular chondrocytes, fetal nasal cells are transplanted into patients, and in the case of polio infection, patients are given injections of fetal muscle tissue.⁴ The medical use of fetal tissue became a topic of controversy in Japan when patients with spinal cord injuries due to accidents received transplants of nasal membrane cells from fetuses aborted in China.⁵

The Advisory Committee on the Use of Human Stem Cells in Clinical Research, appointed by the Health Sciences Council of the Japanese national Ministry of Health, Labor and Welfare (MHLW), convened from 2002 to 2006 to develop “Guidelines for the Use of Human Stem Cells in Clinical Research.” During this process, there were discussions regarding the use of aborted fetuses for stem cell research.⁶ Initially, the committee included stem cells taken from aborted fetuses as part of its investigation, but later decided that “clinical research using human stem cells taken from fetuses (including those that were dead)” would be excluded from the guidelines they were developing.⁷ This paper focuses mainly on studies regarding the use of aborted fetuses that were published after the establishment of the committee’s guidelines, specifically on their suggestions regarding instructional requirements as part of the informed consent process for donating fetal tissue for research.

1. Conditions governing the donation of fetal tissue

Different countries as well as international institutions, such as the Council of Europe and the World Medical Association, have their own regulations governing the use of fetal tissue obtained from induced abortions for research. Most countries and institutions state that fetal tissue use in research is permissible as long as certain conditions are met. These conditions can be broadly grouped into three categories.⁸

First, there are conditions to be met for ethics committee approval. For example, Section 35 of the 1972 Peel Report stipulated that ethics committee approval was to be granted, provided the committee agreed (a) on the validity of the research, (b) that the required information could not be obtained in any other way, and (c) that the investigators had the necessary facilities and skill.⁹ The Peel Code, given at the end of the Peel Report, reemphasized these points. The British Medical Association (BMA) “Guidelines on the Use of Fetal Tissue” (1988), which served as a bridge between the Peel Report and the Polkinghorne Report (1989) that followed, stipulated that every project involving transplantation of fetal tissue must be approved

by the local ethical research committee.”¹⁰ Section 7.5 of the Polkinghorne Report similarly specified that “The ethics committee should satisfy itself *inter alia* of the validity of the research, that the required information cannot be obtained in any other way, and that the investigators have the necessary facilities and skill.”¹¹

The Australian National Health and Medical Research Council (NHMRC)’s “Statement on Ethical Conduct in Research involving Humans” (1992) stipulates that “The research must be conducted only in institutions that have a properly constituted ethics committee, and only according to written protocols approved by the ethics committees of all institutions involved.”¹² The 2002 revision of the American Medical Association’s (AMA) “Current Opinions of the Council on Ethical and Judicial Affairs: E-2.10 Fetal Research Guidelines,” states that “competent peer review committees, review boards, or advisory boards should be available, when appropriate, to protect against the possible abuses that could arise in such research.”¹³ Although the Swiss Academy of Medical Science’s “Medico-Ethical Guidelines for the Transplantation of Human Fetal Tissue” (1998) is specific to the individual transplant, section 1.7 states that: “Any transplantation of foetal tissue must take place within the framework of a research project that has been checked and approved by the responsible Ethical Committee.”¹⁴

The second category of conditions relates to preventing situations in which a woman purposely gets pregnant with the intention of having an abortion in order to donate the fetus to research. In such cases, all of the following conditions apply: 1) no compensation for the donation of fetal tissue can be offered, 2) the woman donating the fetal tissue may not designate who the recipient will be, 3) mutual anonymity must be maintained between the donor of the fetal tissue and the transplant recipient, 4) the timing of the abortion and the procedure must not be changed, and 5) the decision to donate must not precede the decision to abort.

Finally, there are conditions related to donor consent. Although conditions regarding the father of the fetus may vary (for example: 1) When possible, obtaining the consent of “the male partner of the pregnant woman,” that is, the

person thought to be the father, is also needed, 2) “The male partner of the pregnant woman” must not object to the donation, or 3) The woman’s consent alone is sufficient, since the woman’s consent is always essential.

Next, we will look at how information should be provided to potential donors of fetal tissue, based on recent research focused on what is involved in a woman’s consent for donation.

2. The relationship between the decision to abort and the decision to donate

Let us revisit what the Polkinghorne Report says regarding women’s consent to donate fetal tissue.

4.2 It has been argued that knowledge of the use of fetal tissue could influence a mother’s decisions to have her pregnancy terminated. It has been suggested that the use of fetal tissue could place women under pressure when reaching a decision or result in more abortions taking place. It has even been put to us that someone could become pregnant in order to make a fetus available for medical use. In our view, pregnancy undertaken to such an end would be an ethically unacceptable use of the fetus as an instrument (treating it as a “thing”). It is not possible fully to discern people’s motivations, but it is possible to limit the degree to which morally dubious wishes can be implemented. To this end we recommend, not only the separation of the decisions relating to abortion and the subsequent use of fetal tissue, but also procedures which will make it impossible for a mother to specify that fetal tissue, which she makes available, should be used in a particular way.

The Polkinghorne Report was concerned that women might get pregnant and abort the pregnancy with the aim of donating fetal tissue: “It has been argued that knowledge of the use of fetal tissue could influence mothers’ decisions to have their pregnancies terminated.” Was this a reasonable concern? A number of studies have looked at what women think about fetal tissue donations, and these studies are summarized below.

First, in 1994, Anderson et al.¹⁵ surveyed 527 women attending a large family-planning clinic in the center of Edinburgh and 167 women attending the Royal Infirmary of Edinburgh, all of whom were pregnant and requesting terminations. Only 6% of the women said they thought it was unjustifiable to use fetal tissue for research. Of the 94% of women who felt that research use was justifiable, 87% felt that research for fetal tissue transplantation was right in principle, and 86% of them would allow their own fetus to be used.

In 1995, Martin et al. published a study conducted in Toronto, of a random sample of 475 women, aged 18-40 years, selected from the family practice registry of an urban teaching hospital. Of the 272 responses, 266 were used for their analysis.

A total of 32 (12.0%) reported that they would be more likely to have an abortion if they could donate tissue for fetal tissue transplantation, 178 (66.9%) stated that they would not be more likely to do so, and 56 (21.1%) were uncertain. Furthermore, 122 (45.9%) of the women who said they would consider an abortion if they became pregnant were asked how they would feel about having an abortion if they knew that tissue from the fetus could help someone suffering from Parkinson’s disease; of a total of 112 responses (some from outside the pool considering abortion) with 83 (45.6%) stating that they would feel better, 4 (2.22%) worse, and 25 (13.7%) uncertain.¹⁶

More recently, in 2008, Pfeffer published a study using focus group discussions to find out what matters to British women when they think about donating an aborted fetus for stem cell research and how stem cell research and therapies might influence their views.¹⁷ The next section looks at this study in more detail.

3. What do women think of using aborted fetuses in research?—Pfeffer’s study

Pfeffer’s study recruited 41 participants into 6 focus groups. The recruiter excluded women who had undergone a termination under section E of the grounds allowed for abortion, in the British Abortion Act of 1967, (if the child were born, it would suffer from physical or mental

abnormalities). Potential participants were provided with an information sheet outlining the purpose of the research and what participation would involve. The facilitator asked participants to discuss the donation of aborted fetuses in general; how, when, where, and by whom women undergoing an abortion should be approached about donating the fetus to stem cell research; the kind of information they should be given; and if and why donation of an aborted fetus might differ from donation of other body tissue.

Pfeffer extracted several points from this study. First, she mentioned the words used. Where the topic under discussion was somehow troubling, participants preferred “fetus” to “baby” and occasionally even avoided that term altogether, by using words or phrases which depersonalized it altogether, such as “a bunch of cells,” “dead matter and it doesn’t do any growing,” “a thing,” or “an accident.”

Second, Pfeffer mentioned how participants responded to questions about donating aborted fetuses to research with an example of the utilitarian position. Stem cell research was welcomed as a “good thing,” and participants in every group approvingly mentioned the therapeutic goals. However, Pfeffer pointed out that participants’ enthusiasm for medical research noticeably diminished as the discussion developed. By the end of the focus groups, participants tended to refuse donation altogether.

Finally, Pfeffer pointed out that participants were unclear about the nature of stem cell research.

4. Suggestions from a comparison of Pfeffer’s study with a Japanese interview survey

Saito conducted an interview survey of 18 people who could potentially be asked to donate eggs or fertilized eggs for research on human embryos (distinct from Pfeffer’s study of women considering abortion). The sample consisted of 3 people being treated for infertility, 8 for gynecological conditions, 2 for gender dysphoria, and 5 other people with positions of interest on this issue.¹⁸ The first finding was that virtually all the participants said that if they were asked to donate embryos or eggs to research, it would be too difficult for them to understand what

the research entailed, including aspects such as what the purpose of the research was, why their cooperation was being requested, and how donation would benefit society. Pfeffer’s study similarly suggested that the focus group participants did not have a clear understanding of what stem cell researchers were actually doing in their labs. Examples of participants’ questions included: Did the researchers use the entire fetus? Did they use organs and cells? Was the fetus still alive during the experiment? If so, when an organ was removed, did they try to revive the fetus and keep it alive? Or, was removal more like getting a blood test? Both of these studies suggest that women were likely to be asked for their consent when they did not have an adequate understanding of what the research entailed.

Moreover, Saito described how those whose consent was actually requested had said that it was difficult to understand what level of research they would be donating to, whether they would directly benefit from it, or whether it was foundational research that would make a social contribution. These responses mirrored that of a focus group participant in Pfeffer’s study, who said, “I think a lot of us do not know what stem cell research actually is.” Women being asked to donate to research may feel they are being asked for their consent without an adequate understanding of what that research is.

Furthermore, Saito noted that participants with gender dysphoria (GD), gynecological conditions, and infertility feel differently with regards to donating gametes and embryos to research, and calls attention to the need to take their different feelings into consideration. Saito’s observation is consistent with Pfeffer’s view that the ways people think and talk about their fetuses differ, depending on whether the child was lost due to miscarriage, fetal abnormalities, or other reasons. Other researchers have also focused on the importance of women’s word choice and its relationship with their attitudes toward their fetuses. Tsuge, for example, focused on the connotations of the phrase “surplus embryo,” which could connote the researcher’s perception that if an embryo were to be disposed of, it should be fine to use it for research. Saito describes how perceiving things as potential waste or something that could be discarded plays a role in researchers’ ability to see eggs, fertilized

eggs, and fetuses as raw materials or resources, and suggests that one aspect of research-related word choice is that it influences how society in general relates to research.¹⁹

In addition, Saito interviewed the potential egg donors regarding their wishes on what level of explanation they would need to be able to give informed consent. Saito provides examples of concerns raised by interviewees, including: “To properly listen to explanations about every use, understand and consent to them would take considerable time,” and, “It seems to me that since we do not understand the current state of the use of eggs and embryos in research, you cannot simply say that ‘it will be fine if just the people who get a good explanation and consent, donate!’” There is reason to assume that these comments would apply equally to explanations provided regarding the use of aborted fetuses.

Women are being asked to consider donating their aborted fetus at the very moment when they are about to go through with a difficult personal decision to abort the pregnancy, a decision that still involves significant social stigmatization.

For example, the Polkinghorne Report states in section 2. “Ethical Basis”, that there were objections to using tissue obtained by induced abortion. A number of submissions suggested that the act of inducing abortion is so morally reprehensible that it taints beyond acceptability any possible beneficial use of the fetal material so obtained—and that, consequently, a woman who decided to have an abortion (which should be condemned) was, morally, no longer in a position to decide the use of the fetus.

While taking these kinds of opinions into account, the Polkinghorne Report authors state that they are unable to endorse them (2.6). Regarding the use of aborted fetuses, they note that the use of fetal tissue from termination of pregnancy has been justified by analogy with the use of human organs that have become available as a result of morally questionable circumstances, such as careless accidents or even murder (2.8). However, the report also notes viewpoints questioning the analogy between using an aborted fetus and using organs that became available as a result of an accident or other misfortune, as not entirely appropriate, since the person (the woman) consenting to the use of the specimen also made the specimen

available for use by deciding to terminate it (i.e., to abort it). That is, these viewpoints seem to challenge this analogy based on the belief that the decision to abort is the woman’s decision to end her special relationship with the fetus and that having destroyed that relationship, she should no longer be allowed to make any decision regarding its use.

After listening to and studying many different viewpoints in this way, the Polkinghorne Report ultimately states that “because abortion is a decision of moral ambiguity and perplexity for many, reached only through a conflict of considerations, it seems too harsh a judgment of the mother’s relation to her fetus to suppose that she is no longer in a special position with regard to it, following an abortion” (2.8), and recommends that “fetal tissue which has become available following spontaneous abortion or death in utero should be dealt with in the same way as tissue derived from therapeutic abortion” (2.9).

The Advisory Committee on the Use of Human Stem Cells in Clinical Research (of the MHLW Health Sciences Council) did not hold discussions on points raised in the Polkinghorne Report, such as whether only tissue obtained from spontaneous miscarriages should be used or whether a person deciding to have an abortion should be able to make the decision regarding the use of the fetus (regardless of whether more weight should be given to the moral condemnation of abortion or to the woman’s having terminated her relationship with the fetus). Therefore, these viewpoints have not been adequately discussed in Japan. However, as we consider the Polkinghorne Committee’s argument on why a person deciding to have an abortion should still be able to make the decision regarding use of the fetus, the opinion of one of Saito’s participants seems reasonable: that “...it would seem callous to refuse to make the donation after being told it would be for a patient with an intractable disease.” In situations where pregnant women opting for elective abortion are asked to consent freely to the use of the aborted fetus, the issue that especially needs to be discussed is the possibility that the women may be driven to consent to donate in order to make amends for having had the abortion.

Similarly, one could consider an opinion from another of Saito’s participants: “Depending

on the person, they may be overwhelmed by their feelings due to their surgery (an ovarian resection), so asking them to donate the ovary before the operation (whatever the purpose) would be unrealistic, wouldn't it? I think some people would also feel hurt." Another relevant issue concerning the timing of a donation inquiry is found in the opinion of a woman in one of Pfeffer's focus groups, who said, "It's terrible [to ask] on the day [of the operation]. I really think that's awful." Beginning with the World Medical Association's Statement on Fetal Tissue Transplantation, which states that: "A final decision regarding abortion is made before initiating discussion of the transplantation use of fetal tissue"²⁰, most guidelines stipulate that the informed consent process take place in the same order: after a woman has decided to have an abortion, she is given an explanation regarding the uses of fetal tissue, and *then* her consent to donate the fetal tissue may be obtained. As discussed previously, this is based on the idea that the decision to abort must precede the decision to donate, from the perspective that women donating fetal tissue should be prevented from becoming pregnant in order to make the donation, and from designating the recipient of the tissue. However, because it is not realistic in practice to seek consent after the abortion has been performed, an explanation regarding the use of fetal tissue is to be provided after the final decision to abort has been made, but before the abortion is performed.

Although research about using aborted fetuses may not be directly performed on pregnant women, suitable care should be taken when obtaining informed consent from them. This is important, given that "getting an explanation and being asked on the day of the procedure for your consent" has been shown to elicit some bewilderment, that pregnant women constitute a vulnerable population, and that even when donation concerns embryos and eggs, "depending on the person, there are also people who would be hurt [if asked to donate them]." It is clear that when donation concerns an aborted fetus, extreme care must be taken.

Conclusion

This review of the literature from the perspective

of how information should be provided when seeking informed consent from potential donors regarding the use of fetal tissue has highlighted the following points: 1) women who are potential donors are often not in a confidential setting where they can frankly and informally discuss donating fetal tissue with the people around them and collect information 2) these women desire a more complete picture regarding the use of fetuses in research, including what the fetal tissue is used for, what kind of discoveries such research leads to, and what kind of outcomes are expected; but 3) as potential donors, they may have to make their decision without enough information to form a comprehensive picture of the research.

In discussing how donations of fertilized eggs for embryonic stem cell research are sought, Tsuge points out that there are those who fear that the belief that an embryo is the seed of human life will be used to prohibit abortion, even if others feel the fetus is only a foreign body. Tsuge states, "if we try to objectively define what an embryo is, a gap will be created with the everyday perceptions and feelings of women and couples of what an embryo is."²¹ Indeed, Pfeffer has demonstrated that when considering the use of aborted fetuses, women's feelings are extremely diverse.

Historically, the Polkinghorne Report prevented donors from naming the recipient of the fetal tissue and recommended that the donor should not be aware of the future use of the fetal tissue (5.3). A subsequent report, *Human Bodies, Human Choices*, published in 2002 in England, Chapter 15 (Fetal Tissue) states that the Polkinghorne committee's underlying concern of avoiding termination of pregnancy for ulterior motives remains valid. However, the approach of providing only nonspecific consent is increasingly out of step with modern expectations that individuals make choices, including medical choices, on a properly informed basis (15.13).²² Pfeffer and Saito's research could be interpreted as reaffirming the validity of the assertions made in *Human Bodies, Human Choices* from the perspective of women donors. People asked to be donors and those asked to participate in a study sometimes think afterward, "if only I had known that, I would have/have not made that decision." It is understandable if potential donors think they

should be provided with information that enables them to make a decision they will later be able to live with, without reservations. Whoever is presenting an explanation to potential female/male donors needs to examine carefully whether that explanation is in fact “good” enough for each woman/man, considering the diverse views of what is considered sufficient information for them to make the “right” decision.

Endnotes

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- 7 The following press release gives details on the reason for removal of aborted fetuses from consideration in the “Guidelines for the Use of Human Stem Cells in Clinical Research”: Using aborted fetuses for stem cells: Research and ethics continue to run along parallel lines [in Japanese]. *Asahi Shimbun*, morning edition, May 17, 2005, p. 17.
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